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FACT SHEET

AMENDMENTS TO FINAL AIR TOXICS RULE FOR PHARMACEUTICAL PRODUCTION

TODAY'S ACTION

- The EPA is proposing several amendments to its air toxics rule for pharmaceutical production, as the result of a settlement agreement with organizations that appealed the final rule.

- Air toxics, also known as hazardous air pollutants, are those pollutants known, or suspected, to cause cancer and other serious health problems. Air toxics are emitted during the pharmaceutical manufacturing process, which consists mainly of chemical operations used to produce drugs and medication.

- Today's amendments will not change the health and environmental effects of the rule, and they will not change the requirement that new and existing major sources control air toxics emissions.

BACKGROUND

- EPA issued its final air toxics rule for pharmaceutical production in September 1998. That rule required the application of maximum achievable control technology, or MACT, for approximately 100 facilities manufacturing pharmaceutical products.

- Pharmaceuticals manufacturing operations covered by the rule include chemical synthesis, formulation, fermentation and extraction processes. The major air toxics to be controlled include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen and the other pollutants can cause noncancer health effects in humans.

- The final rule is expected to reduce air toxics emissions by 24,000 tons per year -- a 65 percent reduction from 1998 levels. It also reduces volatile organic compound (VOC) emissions, which contribute to the formation of ground-level ozone (smog).

- On November 17 and 20, 1998, petitions for reconsideration and review of the rule were filed in the U.S. Court of Appeals for the District of Columbia Circuit. The Pharmaceutical Research and Manufacturers of America petitioned for reconsideration and review of the final rule, and the Chemical Manufacturers of America and Dow Chemical Company joined the litigation as intervenors.

- Issues raised in the petitions included: the definition of a pharmaceutical manufacturing process; a 98 percent reduction requirement for certain process vents; the applicability of the rule (including to specialty chemical manufacturers); the clarity of the rule; and recordkeeping requirements.

WHAT THE AMENDMENTS WOULD DO

- To address issues raised in the petitions, the proposed amendments include several changes, including a change to the definition of "process," so that a process ends when either a finished form of a drug or an "intermediate" form of the drug is put in equipment for storage.

- The proposed amendments also:

  - Clarify when an "intermediate" becomes a pharmaceutical chemical.

  - Offer an alternative to meeting a 2,000 pound-per-year mass emission limit per process, for up to seven processes.

  - Change language to clarify that a grandfathering provision for certain vents subject to a "98 percent requirement" apply to the vents control device and not the process.

  - Includes changes to an alternative standard for combustion devices and dense gas systems with noncombustion devices. The amended alternative standard requires additional monitoring in lieu of correcting for the addition of supplemental gas.

  - Streamlines recordkeeping and reporting requirements for facilities complying with the alternative standard.

- In addition, today's proposed action amends provisions in the rule that allow industry to comply through an alternative, pollution prevention-based standard. The alternative standard requires significant reductions in the amounts of toxic air pollutants used during the manufacturing process. The amendments would allow facilities to focus on improving processes by reducing solvent use in the manufacture of a single intermediate or through the combined steps in the manufacture of the final drug product.

FOR MORE INFORMATION

- For further information about the proposal, contact Randy McDonald of EPA's Office of Air Quality Planning and Standards at (919) 541-5402.

- EPA's Office of Air and Radiation's homepage on the internet contains a wide range of information on the air toxics program, as well as many other air pollution programs and issues. The Office of Air and Radiation's home page address is: http://www.epa.gov/oar.